IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KISSEI PHARMACEUTICAL CO., LTD., WATSON LABORATORIES, INC. and ACTAVIS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HETERO USA INC., HETERO LABS LIMITED and HETERO LABS LIMITED, UNIT III,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Kissei Pharmaceutical Co., Ltd., Watson Laboratories, Inc., and Actavis Inc., (collectively "Plaintiffs"), by and through their undersigned counsel, bring this Complaint for patent infringement against Defendants Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited, Unit III (collectively "Hetero" or "Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA") submitted by and/or for the benefit of Hetero with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Plaintiffs' RAPAFLO® capsules, 4 mg and 8 mg, that are sold in the United States.

THE PARTIES

2. Plaintiff Kissei Pharmaceutical Co., Ltd. ("Kissei") is a Japanese corporation, having its principal place of business at 19-48, Yoshino, Matsumoto City, Nagano Prefecture 399-8710, Japan. Kissei is an R&D-oriented pharmaceutical company that contributes to the

health of people around the world through innovative drug products. Kissei is the owner and assignee of U.S. Patent No. 5,387,603 ("the '603 patent").

3. Actavis, Inc. ("Actavis") is a corporation organized and existing under the laws of the State of Nevada with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Actavis is the exclusive licensee of the '603 patent.

4. Watson Laboratories, Inc. ("Watson") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 577 Chipeta Way, Salt Lake City, Utah 84108. Watson is a wholly-owned subsidiary of Actavis, and is the registered holder of approved New Drug Application No. 22-206.

5. On information and belief, Defendant Hetero USA, Inc. ("Hetero USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854, and is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at W/K Incorporating Services, Inc., 3500 South DuPont Highway, Dover, DE 19901) for the receipt of service of process.

6. On information and belief, Defendant Hetero Labs Limited ("Hetero Labs") is an Indian corporation having a principal place of business at Survey No. 10, I.D.A., Gaddapotharam Village, Jinnaram Mandal, Medak District, A.P., India.

7. On information and belief, Defendant Hetero Labs Limited, Unit III ("Hetero Labs Unit III") is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar Hyderabad – 500 018 Andhra Pradesh, India.

8. On information and belief, both Hetero Labs and Hetero Labs Unit III are parent corporations of Hetero USA.

9. On information and belief, Hetero USA acts as the agent of Hetero Labs and Hetero Labs Unit III.

10. On information and belief, Hetero Labs, Hetero Labs Unit III, and Hetero USA manufacture and sell various generic drug products and regularly conduct business throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

12. Upon information and belief, Hetero USA, Hetero Labs, and Hetero Labs Unit III are subject to personal jurisdiction in this District by virtue of their presence and activities in the State of Delaware, and by having systematic and continuous contacts with the State of Delaware so as to reasonably allow personal jurisdiction to be exercised over them.

13. Personal jurisdiction over Hetero USA and Hetero Labs is proper because they have previously admitted to jurisdiction in this Court, and have availed themselves of this forum by asserting declaratory judgment counterclaims for the purpose of litigating a patent dispute. *See Forest Laboratories, Inc. et al. v. Torrent Pharmaceuticals Ltd., et al.*, C.A. No. 12305 (D. Del. June 4, 2012.)

14. Upon information and belief, Hetero USA is a Delaware corporation, is registered to do business in Delaware, and is the U.S. regulatory agent for Hetero Labs and Hetero Labs Unit III.

15. Upon information and belief, Hetero Labs Unit III is a division or part of Hetero Labs. Hetero Labs' website, located at http://www.heterodrugs.com/mfg-API-facilities.shtml, describes Unit III as an API manufacturing facility of Hetero Labs.

16. Upon information and belief, Hetero USA is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. Upon information and belief, Hetero USA, either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes its pharmaceutical products in Delaware. Upon information and belief, the acts of Hetero USA discussed in this Complaint were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Hetero Labs and Hetero Labs Unit III. In a letter dated May 9, 2013, notifying Kissei, Watson, and Actavis of the submission to FDA of Hetero's ANDA No. 204793, Hetero USA described itself as "the U.S. Regulatory Agent for Hetero Labs Limited Unit III."

17. Upon information and belief, this Court has personal jurisdiction over Hetero USA by virtue of, *inter alia*: (1) its incorporation in the State of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware for the service of process; (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its previous admission that it is subject to this Court's jurisdiction.

18. Upon information and belief, Hetero Labs formulates, develops, markets, and sells active pharmaceutical ingredients ("API"), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical

formulations (collectively, "Hetero's products"). Upon information and belief, Hetero Labs Unit III manufactures the API used in Hetero's products. Hetero Labs and Hetero Labs Unit III, through their U.S. regulatory agent, Hetero USA, routinely file ANDAs seeking FDA approval to market its products in the United States.

19. Upon information and belief, Hetero Labs and Hetero Labs Unit III, directly or through Hetero USA and/or through one or more of its wholly-owned subsidiaries, affiliates, agents, distributors, or parent corporation is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero Labs and Hetero Labs Unit III, either directly or through Hetero USA and/or through one or more its wholly-owned subsidiaries, agents, and/or distributors, formulates, manufactures, markets, and/or distributes a substantial volume of its pharmaceutical products in the State of Delaware.

20. Hetero USA's acts and continuous and systematic contacts with the State of Delaware, as an agent of Hetero Labs and Hetero Labs Unit III, are also attributable to Hetero Labs and Hetero Labs Unit III for jurisdictional purposes.

21. Upon information and belief, Hetero USA, Hetero Labs, and Hetero Labs Unit III operate as an integrated business that is controlled by Hetero Labs.

22. Upon information and belief, this Court has personal jurisdiction over Hetero Labs and Hetero Labs Unit III by virtue of, *inter alia*: (1) their presence in Delaware, including through Hetero USA; (2) their course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware; (3) their purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (4) their previous admission that it is subject to this Court's jurisdiction.

23. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTUAL BACKGROUND

A. The '603 Patent

24. On February 7, 1995, the United States Patent and Trademark Office duly and lawfully issued the '603 patent, entitled "1,5,7-Trisubstituted Indoline Compounds and Salts Thereof" to inventors Makio Kitazawa, Masaaki Ban, Kosuke Okazaki, Motoyasu Ozawa, Toshikazu Yazaki, and Ryoichi Yamagishi. Kissei is the assignee of the '603 patent. A true and accurate copy of the '603 patent is attached as Exhibit A to this Complaint.

25. The '603 patent claims, *inter alia*, the silodosin compound (the active ingredient in RAPAFLO®), a pharmaceutical composition of silodosin, and a method for the treatment of dysuria by administering to a mammal or a human a therapeutically effective amount of silodosin.

B. RAPAFLO® Drug Product

26. Plaintiff Watson is the registered holder of New Drug Application No. 22-206 for RAPAFLO® capsules, 4 mg and 8 mg, which contain silodosin as the active ingredient. The FDA approved NDA No. 22-206 on October 8, 2008.

27. RAPAFLO® capsules, 4 mg and 8 mg, are indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH), and are marketed and sold in the United States by a subsidiary of Actavis.

28. The '603 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the "Orange Book") with respect to RAPAFLO® capsules, 4 mg and 8 mg dosage forms.

C. Infringement by Hetero

29. On information and belief, Hetero has submitted ANDA No. 204793 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to engage in the commercial manufacture, use, and sale of silodosin capsules, 4 mg and 8 mg ("Hetero's ANDA Products"), as a generic version of RAPAFLO®, before the expiration of the '603 patent.

30. Upon information and belief, Hetero's ANDA No. 204793 contains information to show that Hetero's ANDA Products (a) are bioequivalent to RAPAFLO® 4 mg and 8 mg capsules, (b) have the same active ingredient as RAPAFLO® 4 mg and 8 mg capsules, (c) have the same route of administration, dosage form, and strength as RAPAFLO® 4 mg and 8 mg capsules, and (d) have the same, or substantially the same, proposed labeling as RAPAFLO® 4 mg and 8 mg capsules.

31. By letter dated May 9, 2013 (the "Notice Letter"), purporting to be a "Notice of Paragraph IV Certification – ANDA 204793, entitled 'Silodosin Capsules, 4 mg and 8 mg,'" Hetero notified Kissei, Watson, and Actavis that it had submitted ANDA No. 204793 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of Hetero's ANDA Products, which are generic versions of RAPAFLO® 4 mg and 8 mg capsules, prior to the expiration of the '603 patent.

32. Kissei did not receive the Notice Letter until May 13, 2013.

33. Actavis did not receive the Notice Letter until on or about May 10, 2013.

34. Watson did not receive the Notice Letter until on or about May 10, 2013.

35. Upon information and belief, Hetero made, and included in its ANDA No. 204793, a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that

the claims of the '603 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Products.

36. The Notice Letter alleges that the '603 patent is invalid, unenforceable, and/or will not be infringed by "the manufacture, use, or sale" of Hetero's ANDA Products, but does not provide any valid basis for these allegations.

37. Hetero's submission of ANDA No. 204793 to the FDA constitutes infringement of the '603 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, and/or import of Hetero's ANDA Products into the United States would infringe the '603 patent under 35 U.S.C. § 271(a)-(c).

COUNT I
(Infringement of U.S. Patent No. 5,387,603)

38. Plaintiffs expressly incorporate by reference and reallege paragraphs 1-37, as if fully set forth herein.

39. Upon information and belief, Hetero's ANDA Products, together with their package inserts, and their use infringe one or more claims of the '603 patent.

40. Upon information and belief, when Hetero filed ANDA No. 204793, it was aware of the '603 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '603 patent was an act of infringement.

41. Hetero was aware of the existence of the '603 patent at least as of the date it sent the May 9, 2013 Notice Letter. On information and belief, Hetero has the specific intent to induce direct infringement of one or more claims of the '603 patent at least by resellers, pharmacies, health care professionals and end users of Hetero's ANDA Products.

42. Upon information and belief, Hetero's submission of ANDA No. 204793 for the purposes of obtaining approval to engage in the commercial manufacture, use and sale of

Hetero's ANDA Products, prior to the expiration of the '603 patent, is an act of infringement of one or more claims of the '603 patent under 35 U.S.C. § 271(e)(2)(A).

43. Unless enjoined by this Court, upon FDA approval of ANDA No. 204793, Hetero will infringe the '603 patent under 35 U.S.C. §271(a) by making, using, offering to sell, importing, and/or selling Hetero's ANDA Products in the United States.

44. Unless enjoined by this Court, upon FDA approval of ANDA No. 204793, Hetero will induce infringement of the '603 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Hetero's ANDA Products in the United States. On information and belief, upon FDA approval of ANDA No. 204793, Hetero will intentionally encourage acts of direct infringement with knowledge of the '603 patent and knowledge that its acts are encouraging infringement.

45. Unless enjoined by this Court, upon FDA approval of ANDA No. 204793, Hetero will contributorily infringe the '603 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Hetero's ANDA Products in the United States. On information and belief, Hetero has had and continues to have knowledge that Hetero's ANDA Products are especially adapted for a use that infringes the '603 patent and that there is no substantial non-infringing use for Hetero's ANDA Products.

46. Unless Hetero is enjoined from infringing the '603 patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law, including irreparable harm within the State of Delaware and this Judicial District.

COUNT II
(Declaratory Judgment as to U.S. Patent No. 5,387,603)

47. Plaintiffs expressly incorporate by reference and reallege paragraphs 1-46, as if fully set forth herein.

48. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

49. Upon information and belief, Hetero has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell, and/or import Hetero's ANDA Products into the United States prior to expiration of the '603 patent.

50. Upon information and belief, Hetero intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Hetero's ANDA Products immediately and imminently upon final FDA approval of ANDA No. 204793.

51. Upon information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Hetero's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Hetero's ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '603 patent.

52. Upon information and belief, Hetero's infringing commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Hetero's ANDA Products set forth herein will begin following FDA approval of ANDA No. 204793.

53. Upon information and belief, Hetero has been aware of the existence of the '603 patent, and has no reasonable basis for believing that the commercial manufacture, use, offer for sale, sale and/or importation into the United States of Hetero's ANDA Products will not infringe, contribute to the infringement thereof, and/or induce the infringement of the '603 patent, thus rendering this case "exceptional," as that term is set forth in 35 U.S.C. § 285.

54. Upon information and belief, Hetero maintains, and Plaintiffs deny, that the '603 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's ANDA Products. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Plaintiffs and Hetero regarding whether Hetero's commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's ANDA Products according to ANDA No. 204793 will infringe one or more claims of the '603 patent. Plaintiffs are thus entitled to a declaration that Hetero's commercial manufacture, use, sale, offer for sale, and importation into the United States of Hetero's ANDA Products according to ANDA No. 204793 will infringe one or more claims of the '603 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the '603 patent is valid and enforceable;

B. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Hetero's submission to the FDA of ANDA No. 204793 to obtain approval for the commercial manufacture, use, and sale of Hetero's ANDA Products before the expiration date of the '603 patent was an act of infringement of the '603 patent;

C. A judgment that Hetero has infringed one or more claims of the '603 patent;

D. A declaration that Hetero's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Hetero's ANDA Products would infringe one or more claims of the '603 patent;

E. A judgment that Hetero's infringement of the '603 patent has been willful and deliberate;

F. A determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of Hetero's ANDA No. 204793, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be a date that is not earlier than the expiration of the '603 patent and any additional periods of exclusivity;

G. An order preliminarily and permanently enjoining Hetero and its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from infringing the '603 patent;

H. A judgment that this is an exceptional case and awarding Kissei, Watson, and Actavis their attorney fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

I. Awarding costs and expenses in this action; and

J. Such other and further relief as this Court may deem just and proper.

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